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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/791,103

03/02/2004

Paul DiCarlo

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EXAMINER

KILIMAN, LESZEK B

ART UNIT

PAPER NUMBER

1794

NOTIFICATION DATE

DELIVERY MODE

03/19/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/791,103	<b>Applicant(s)</b> DICARLO ET AL.	
	<b>Examiner</b> leszek b. kiliman	<b>Art Unit</b> 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 17, 25-27 and 29-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 17, 25-27, 29-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

In view of the Appeal Brief filed on 11-6-09, PROSECUTION IS HEREBY REOPENED. The rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Callie E. Shosho/

Supervisory Patent Examiner, Art Unit 1794

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3,6-10,25-27,29,34-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Lanphere (USP 7,449,236)

The applied reference has a common Invenor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention “by another,” or by an appropriate showing under 37 CFR 1.131.

Initially, please note that although the reference does not specifically state that the embolic particles comprise shape memory material, the reference in fact describe such material in details, (see column 5, lines 16-60 and specifically column 5, line 49-59 and column 7,lines 42-50).

See abstract, column 2, lines 52-60 for polymers other than polyvinyl alcohol; column 3, lines 57-67 and column 4, lines 1-13 for description of particles; column 5, lines 15-60 for

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structure and properties of the embolic particles; column 7, lines 41-50 for properties of particles; column 8, lines 7-35 for polymers used in formation of particles including PU and PMMA, alginate; Column 13 line 10 through column 14, lines 24 for use of particles with therapeutic agents including claimed agents; Also, please note that in column 14, lines 1-23 the applied reference teaches therapeutic agents that can be included in particles (meaning in cavities) and some may be radioactive species that may include well known and used in the art radiopaque materials such as gold etc. Regarding claims 34-37, please note that in column 8 lines 23-35 the prior art reference teaches a second non-solid embolic materials in the form of gel. Regarding claim 36, the particles of the prior art reference are capable of increasing in volume by inclusion of liquids

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3,6,30,31 are rejected under 35 U.S.C. 102(e) as being anticipated by Buiser (USP 7588780).

Initially, please note that although the reference does not specifically state that the embolic particles comprise shape memory material, the reference in fact describe such material in details. See specifically column 4, lines 36-52 wherein the elastic recovery from compression is described.

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See abstract, column 1, lines 24-29, column 2, lines 1-44 for particle properties; column 3, lines 11-35 and column 4, lines 15-52 for shape properties and use; column 6, lines 43-67 for other polymers and additives that are not PVOH; column 13, lines 1-13 for other shapes of particles.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4,5,17,32-33,39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buiser'780 or Lanphere'236.

The applied references teach that it is known in the art to make and use embolic composition (see the above rejections). The applied references do not specifically teach that shape memory particle may comprise and alloy or have a groove, or include particles having a different size, or include particles having a different hardness. However, the prior art teaches that embolic compositions are used in number of applications ( See USP'236 ) that may include harsh conditions or require different spectral properties. It would have been obvious to include alloys in compositions of embolic particles to improve mechanical and spectral properties. Also,

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the prior art teaches that particles may be shaped (see USP'780). It would have been obvious to include grooves in particles as well as include particles of different sizes, since such would improve number of different compositions for a different medical applications. Also, it is thought in the prior art references that hardness of particle is dependent on the region of particle (see USP'236 column 3, lines 56-60, compressibility). It would have been to optimize particle hardness according to conditions of use. Regarding claim 39, the prior art does not teach polyethylene terephthalate. However, the prior art teaches that other polymers may be included (see USP'780 column 6, lines 46-53) and gives examples of commonly used polymers. It would have been obvious to one having ordinary skill in the art at the time of the invention to use PET in the prior art inventions since such would optimize mechanical properties of particles.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to leszek b. kiliman whose telephone number is 571-272-1509. The examiner can normally be reached on M-T, 6.30-5.00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, calie shosho can be reached on 571-272-1123. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lk

/leszek b kiliman/

Primary Examiner, Art Unit 1794